

Applicants : Alexander Gad et al.
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Page 56, paragraphs 1-2:

The present invention provides molecular weight markers for accurate determination of the molecular weight of glatiramer acetate and other copolymers. The present invention further provides a plurality of molecular weight markers for determining the molecular weight of glatiramer acetate and other copolymers which display linear relationships between molar ellipticity and molecular weight, and between retention time and the log of the molecular weight. The molecular weight markers also optimally demonstrate biological activity similar to glatiramer acetate or corresponding copolymers and can be used for treating or preventing various immune diseases. In addition, the subject invention provides pharmaceutical compositions for the treatment of immune diseases comprising a polypeptide having an identified molecular weight and an amino acid composition corresponding to glatiramer acetate or a terpolymer.

In the Claims

Please cancel claims 20, 34-35, 47-49, 70-91 and 94-122 without prejudice to applicants rights to pursue the subject matter of these claims in this or a related application. In addition, please add new claims 123-143 as follows:

123. (New) A method of treating or preventing an autoimmune disease in a mammal comprising administering to the mammal a purified polypeptide having the amino acid sequence set forth in SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6 or SEQ ID NO:7, or a mixture of the purified polypeptides.

124. (New) The method of claim 123 wherein the purified polypeptide

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consists entirely of L-amino acids.

125. (New) The method of claim 123 wherein the purified polypeptide consists entirely of D-amino acids.

126. (New) The method of claim 123, wherein the purified polypeptide has the amino acid sequence set forth in SEQ ID NO: 1.

127. (New) The method of claim 123, wherein the purified polypeptide has the amino acid sequence set forth in SEQ ID NO: 2.

128. The method of claim 123, wherein the purified polypeptide has the amino acid sequence set forth in SEQ ID NO: 3.

129. (New) The method of claim 123, wherein the purified polypeptide has the amino acid sequence set forth in SEQ ID NO: 4.

130. (New) The method of claim 123, wherein the purified polypeptide has the amino acid sequence set forth in SEQ ID NO: 5.

131. (New) The method of claim 123, wherein the purified polypeptide has the amino acid sequence set forth in SEQ ID NO: 6.

132. (New) The method of claim 123, wherein the purified polypeptide has the amino acid sequence set forth in SEQ ID NO: 7.

133. (New) A method of treating or preventing an autoimmune disease in a mammal comprising administering to the mammal a pharmaceutical composition consisting essentially of a purified polypeptide having the amino acid sequence set forth in SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6 or SEQ ID NO:7, or a mixture of the purified polypeptides, and a pharmaceutically

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acceptable carrier.

134. (New) The method of claim 123 or 133 wherein said autoimmune disease is a B cell mediated autoimmune disease, a T cell mediated autoimmune disease, a demyelinating disease, an inflammatory disease, rheumatoid arthritis, osteoarthritis, multiple sclerosis, autoimmune hemolytic anemia, autoimmune oophoritis, autoimmune thyroiditis, autoimmune uveoretinitis, Crohn's disease, chronic immune thrombocytopenic purpura, colitis, contact sensitivity disease, diabetes mellitus, Graves disease, Guillain-Barre's syndrome, Hashimoto's disease, idiopathic myxedema, myasthenia gravis, psoriasis, pemphigus vulgaris, rheumatoid arthritis, or systemic lupus erythematosus.

135. (New) The method of Claim 134, wherein said autoimmune disease is a B cell mediated autoimmune disease.

136. (New) The method of Claim 134, wherein said autoimmune disease is a T cell mediated autoimmune disease.

137. (New) The method of Claim 134, wherein said autoimmune disease is a demyelinating disease.

138. (New) The method of Claim 134, wherein said autoimmune disease is multiple sclerosis.

139. (New) The method of Claim 134, wherein said autoimmune disease is an inflammatory disease.

140. (New) The method of Claim 134, wherein said autoimmune disease is rheumatoid arthritis.

141. (New) The method of Claim 134, wherein said autoimmune disease

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is osteoarthritis.

142. (New) A method of treating or preventing graft versus host disease (GVHD), host versus graft disease (HVGD) or delayed-type hypersensitivity (DTH) in a mammal comprising administering to the mammal a purified polypeptide having the amino acid sequence SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6 or SEQ ID NO:7.

143. (New) A method of determining molecular weight of glatiramer acetate comprising calibrating a chromatographic apparatus that is used for molecular weight determination with a purified polypeptide having the amino acid sequence SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6 or SEQ ID NO:7 and determining the molecular weight of the glatiramer acetate using the calibrated chromatographic apparatus that is used for molecular weight determination.